REMARKS

Request for Substitution of Sequence Listing based upon Deposit

At the outset, Applicants respectfully request substitution of the sequence listing on file with the sequence listing submitted herewith. Upon resequencing the plasmid, 18GC, identified in the instant application (SEQ ID NOS:3 and 4) at least at page 4, lines 20-22, of the specification as originally filed and Figures 1A-1C, Applicants have noted five nucleotide discrepancies which did not result in any amino acid change in the amino acid sequence, SEQ ID NO:4, as originally filed.

Applicants have deposited the plasmid identified in the application with the ATCC on September 10, 2002. The deposit has been accepted and designated PTA-4654. Applicants, in the instant Response, seek to incorporate the correct sequence into the application with the ATCC deposit, the substitute sequence listing based upon the deposit, amended specification, amended drawings, and declarations. A copy of the papers to accept the sequence of the ATCC deposited organism, filed on December 12, 2002, in a related application, U.S. Application No. 09/886,400, is submitted herewith. Examination of the proper sequences is respectfully requested.

Status of the Claims

Claims 1-12 are currently pending. In the present Response, claims 1-3, 6, 7, and 9 are amended; and claims 13-15 are added. Thus, after entry of these amendments, claims 1-15 are presented for consideration.

Outstanding Rejections

Pursuant to the Office Action, claims 1-12 are rejected under 35 U.S.C. §112, first paragraph. Claims 1-12 are rejected under 35 U.S.C. §112, second paragraph. Claims 1-2 and 5-12 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 2 of U.S. Patent No. 5,958,751. Claims 1-12 are

provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of copending Application No. 10/114,083.

Applicants respectfully traverse all outstanding objections to the specification and rejections of the claims.

Support for the Claim Amendments

Claims 1-3, 6, 7, and 9 have been amended to more particularly describe the invention. Support for the claim amendments can be found in the specification in general. As one of ordinary skill in the art would recognize, α-glycosidic bonds are a generic term for linking sugars with another organic molecule. The α-glycosidic bonds of the instant invention, however, are limited to ones that can be hydrolyzed by an enzyme having α-galactosidase activity. As is known to the skilled artisan, enzymes having α-galactosidase activity can hydrolyze α-1,6 linked α-galactose residues as well as α-D-fucosides. Thus, the skilled artisan would also recognize that α-1,6 galactosyl bonds or α-1,6 galactosidic bonds are also contemplated in the practice of the claimed invention. Amended claim 3 and new claims 14 and 15 find support, *inter alia*, at page 11, lines 10-17, of the specification. Accordingly, Applicants respectfully submit that the amendments do not introduce new matter.

Objections to the Specification

The Patent Office objects to the specification for not complying with the sequence rules. Applicants herewith submit a corrected sequence listing. The instantly submitted sequence listing is supported by the deposit of an organism containing the nucleic acid of the claimed invention, identified as 18GC in the specification. Applicants submit that no new matter is introduced by the corrected sequence listing.

Priority

The Patent Office notes that while the polypeptide of SEQ ID NO:4 in U.S. Application No. 08/613,220 is disclosed in Figure 1 as having 364 amino acids, in a previously submitted

sequence listing SEQ ID NO:4 had 346 amino acids. Applicants submit that the instantly corrected sequence listing SEQ ID NO:4 of the present application and SEQ ID NO:4 in the priority application 08/613,220 are the same. Accordingly, Applicants respectfully submit that the present application is entitled to rely on its priority date of March 8, 1996.

Objections to the Drawings

The Patent Office indicates that the drawings have been review and approved; but objects because of the sequences submitted in the previously filed sequence listing. Applicants submit that Figures 1A-1C accurately depict the nucleic and amino acid sequences of SEQ ID NOS:3 and 4 of the corrected sequence listing submitted herewith. Applicants submit corrected Figures 1A and 5C based upon the nucleic sequence in the ATCC deposit. Accordingly, no new matter is added by the drawing corrections.

Issues under 35 U.S.C. §112, second paragraph

Claims 1 and 6 (and claims 2-5 and 7-12 that depend therefrom) are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite in the recitation of "α-galactose bond," as the Patent Office alleges that the term is unclear. Applicants have replaced the term with "α-glycosidic bond capable of being hydrolyzed by an α-galactosidase," the scope of the term would be well recognized by one of ordinary skill in the art.

Claim 9 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for reciting "a member of the lentil family or bean family, or a combination thereof." Applicants have amended claim 9 to clarify that the method contemplates a compound contained in a member of the lentil family, the bean family or both the lentil and bean families.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-12 based upon 35 U.S.C. §112, second paragraph.

Issues under 35 U.S.C. §112, first paragraph

Claims 1-2 and 5-12 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Patent Office alleges that claims 1-2 and 5-12 are directed to a method for hydrolyzing a genus of bonds with a genus of enzymes having at least 70% amino acid sequence identity to the polypeptide of SEQ ID NO:4. In particular, the Patent Office alleges that there is no disclosure of the function of other enzymes having at least 70% sequence identity to that of SEQ ID NO:4, page 5, lines 20-22, and no disclosure of which bonds are hydrolyzed by enzymes of any function having identity to SEQ ID NO:4. Applicants have amended the claims to specify that the claimed methods utilize enzymes having 70% sequence identity to SEQ ID NO:4 and having α-galactosidase activity. One of ordinary skill in the art, based upon the sequences provided and an assay for testing activity, would be armed with the knowledge to practice the full scope of the claimed invention. Accordingly, Applicants respectfully submit that one of ordinary skill in the art could have concluded that Applicants were in possession of the claimed invention at the time the instant invention was filed.

Claims 1-2 and 5-12 are rejected under 35 U.S.C. §112, first paragraph, because while the specification is enabled for a method for hydrolyzing α-1,6 galactosyl bonds with the enzyme of SEQ ID NO:4, it is alleged that it does not reasonably provide enablement for a method of hydrolyzing any bond with any enzyme which is at least 70% sequence identical to SEQ ID NO:4.

Applicants respectfully submit that the amended claims are not directed to a method of hydrolyzing any bond with an enzyme having at least 70% sequence identity to SEQ ID NO:4. Applicants further submit the specification does reasonably enable a person of ordinary skill in the art to practice the full scope of claims 1-12 as amended. Applicants remind the Patent Office that the specification is directed to the skilled artisan. The skilled artisan is well versed in

protocols used in a laboratory for biological research. Applicants have provided the skilled artisan the polypeptide sequence, SEQ ID NO:4, against which the enzymes of the invention can be referenced. Applicants submit that it would have been a routine matter for practicing the methods of the claimed invention. Thus, the specification reasonably enables one of ordinary skill in the art to practice the full scope of the claimed invention.

The Patent Office alleges that it would take undue experimentation for the skilled artisan to make and use the invention commensurate in scope with the claims because, among other reasons, no information about the critical structural elements required to maintain the desired function is described. Applicants, however, remind the Patent Office that the Federal Circuit in *In re Wands* directed that the focus of the enablement inquiry should be whether the experimentation needed to practice the invention is or is not "undue" experimentation. The court set forth specific factors to be considered.

One of these factors is "the quantity of experimentation necessary." Guidance as to how much experimentation may be needed and still not be "undue" is set forth by the Federal Circuit in, *e.g.*, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*[1] An applicant had claims that were generic to all IgM antibodies directed to a specific antigen. However, only a single antibody producing cell line had been deposited.[2] The PTO had rejected claims that were generic to all antibodies directed to the antigen as lacking an enabling disclosure.

The Federal Circuit reversed, noting that the evidence indicated that those skilled in the monoclonal antibody art could, using the state of the art and applicants' written disclosure, produce and screen new hybridomas secreting other monoclonal antibodies falling within the genus without undue experimentation. The court held that applicants' claims need not be limited to the specific, single antibody secreted by the deposited hybridoma cell line (significantly, the genus of antibodies was allowed even though only one antibody species was disclosed). The court was acknowledging that, because practitioners in that art are prepared to screen large

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[1] *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987).

[2] The cell line was a hybridoma, thus, all of the antibodies it produced had the same structure and activity.

numbers of negatives in order to find a sample that has the desired properties, the screening that would be necessary to make additional antibody species was not "undue experimentation."

Applicants submit that the skilled artisan would know how to make and use the enzymes, based on what is taught in the specification and his or her own knowledge and experience, and be able to practice the method of hydrolyzing α-glycosidic bonds that can be hydrolyzed by an enzyme having α-galactosidase activity with the enzymes described in the instant application. Accordingly, the skilled artisan has sufficient guidance from the specification to practice the claimed methods without undue experimentation.

Claims 1-12 are rejected under 35 U.S.C. §112, first paragraph, for allegedly introducing new subject matter. Applicants respectfully request that Patent Office to consider the corrected sequence listing provided herein. Applicants submit that no new matter has been introduced by the instant amendment.

In light of the amendments and arguments presented herein, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-12 based upon 35 U.S.C. §112, first paragraph.

Issues regarding Double Patenting

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting for allegedly being unpatentable over claim 2 of U.S. Patent No. 5,958,751. Applicants herewith submit a terminal disclaimer to obviate this rejection.

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting for allegedly being unpatentable over claim 1 of copending Application No. 10/114,083. The Patent Office notes that this is a provisional rejection as the allegedly conflicting claims have not in fact been patented. Accordingly, Applicants request that this issue be deferred until agreement on the instant claims is reached.

The Patent Office has advised the Applicants that should claim 3 be found allowable, claim 4 would be objected to for being a substantial duplicate thereof. Applicants have amended claim 3, thereby obviating this rejection.

CONCLUSION

Applicants request that the Examiner reconsider the application and claims in light of the foregoing reasons and amendments and respectfully submit that the claims are in condition for allowance.

If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Applicants have included a check for the extension of time fee. Applicants believe that no additional fees are necessitated by the instant Response. However, in the event any fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 06-1050.

Respectfully submitted,

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